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REMARKS

Claims 1-28, 30-63, 65, 66, 69-84 are pending herein.

Presently pending claims 7, 8, 14, 17-23, 26, 27, 33, 39-49, 51, 53, 55, 58, 59, 62, 65, 66, 69, 70, and 75-79 are withdrawn from consideration by virtue of applicant's species election.

In the Advisory Action of July 3, 2007, the Examiner indicates that Maseda does not satisfactorily meet the limitations of the active region disposed beneath the balloon and thus independent claim 28 and all corresponding dependent claims overcome the cited prior art. No other non-art rejections of these claims are outstanding. Thus it is believed that claim 28 and claims 30-42 depending therefrom are in a condition for allowance.

The above limitation is also found in claim 84 which is also believed to be in condition for allowance.

The Examiner is invited to contact the undersigned to discuss the possibility of an Examiner's amendment to place claim 84 in independent form and to cancel any non-allowed claims.

Rejection of claims 1-6, 9, 12, 13, 15, 16, 24, 25, 50, 54, 56, 57, 61, 71, 72, 80 and 84 under 35 U.S.C. 102(e) over Maseda et al. US 6,514,237 (Maseda)

Claims 1-6, 9, 12, 13, 15, 16, 24, 25, 50, 54, 56, 57, 61, 71, 72, 80 and 84 are rejected under 35 U.S.C 102(e) as being anticipated by Maseda. Applicant respectfully traverses this rejection and its supporting comments.

Applicant respectfully requests that the remarks presented in the response to the first rejection on the merits be incorporated by reference herein. The following remarks emphasize aspects of those remarks and respond to the Examiner's reasons for finding them unconvincing.

Claim 1

Claim 1 is directed to a medical device comprising (a) an elongate body adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis; and (b) an active region comprising a *conductive polymer* disposed over the elongate body *such that the medical device is expanded in at least one radial dimension relative to said axis upon volumetric expansion of the active region.*

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Applicant's claims, should be interpreted as they would be by one of ordinary skill in the art to whom they are directed in light of the specification and the state of the art. *In re Watson*, 186 U.S.P.Q. 11, 20 (Fed. Cir. 1975). That person of ordinary skill would not have interpreted the present claims as reading on the ion exchange polymer-noble metal composites of the reference.

The Examiner urges that claim 1 is broad enough to all the different categories of electroactive polymers, including those of Maseda. More particularly, the Examiner argues that ionic exchange polymer-noble metal composites are inherently conductive and can thus be considered to be conductive polymers in a "broad sense." Applicant respectfully disagrees with the Examiner's analysis.

Enclosing H. Sahoo et al., "Actuators based on electroactive polymers," *Current Science*, Vol. 81, No. 7, 10 October 2001, 743-746, Applicant pointed out in the response to the prior Office Action of September 21, 2006 that ionic polymer metal composites and conductive polymer actuators are distinct classes of material in the electroactive polymer art. One of ordinary skill in the art would, therefore, not confuse conductive polymers like those claimed with ionic polymer metal composites like those described in Maseda.

Moreover, claim 1 requires *both* "volumetric expansion" of the "active region" *and* expansion of the medical device in a "radial dimension." As noted previously, mass transfer of ions into and out of conductive polymer material recited in the claims (e.g., transfer from and into an ionically conductive electrolyte medium associated with the conductive polymer) leads to the volumetric expansion or contraction of the polymer. The ion exchange polymer-noble metal composites of the Maseda reference, however, do not expand. They only bend. In particular, it was previously pointed out that when a voltage is applied, an electric field is set up inside the ionic polymer of an ion exchange polymer-noble metal composite causing the ions (e.g., cations) within the polymer, along with associated hydrated water molecules, to move within the polymer towards one of the electrodes (e.g., the cathode), which movement of within the polymer produces a bend in the EAP towards the other electrode (e.g., the anode). Being self contained, such actuators do not undergo volumetric expansion, as do conductive polymers like those presently claimed, rather they undergo deformation in the form of bending.

The Examiner apparently understands this, but claims that Maseda at col. 3, line 54 teaches that ion exchange polymer-noble metal composites are capable of expanding. Actually,

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this portion of Maseda merely teaches the following: "The activation, via the controller, of the electroactive polymer strands embedded in and/or replacing sections of the flexible probe device may induce movements such as ... expansion..." Nothing in this citation teaches that the composites themselves are capable of expanding.

The Examiner also argues that the Academic Press Dictionary of Science and Technology defines "expansion" as an increase in volume. However, claim 1 is not simply directed to mere "expansion" or even mere "volumetric expansion" which the Examiner might believe embraces the bending of the ion exchange polymer-noble metal composites of Maseda in certain embodiments (see, e.g., the collection of ion exchange polymer-noble metal composite strips 500, which are constrained from movement on their ends and are said to "expand like a balloon" as disclosed in col. 6 and illustrated in Figs. 5 and 5A of Maseda). Rather claim 1 requires "volumetric expansion of the active region" a concept that is neither taught nor suggested by the bending composite strips of Maseda.

Finally, with respect to the quotation from paragraph [0055] of the present specification referred to by the Examiner, the full quote is as follows: "As discussed above, the EAP-containing active region contracts or expands in response to the flow of ions out of, or into, the same. Essentially any electroactive polymer that exhibits contractile or expansile properties may be used in connection with the various active regions of the invention, including those listed above." Thus, the "contractile or expansile properties" being referred to are the contraction or expansion of an EAP-containing active region in response to the flow of ions out of, or into, the same. This portion of the specification is therefore entirely consistent with the language of claim 1 and with applicant's statements. Moreover, based on the design of ion exchange polymer-noble metal composite strips such as those of Maseda, expansion and contraction of this nature would not be possible.

For at least the above reasons, the limitations of claim 1, and the claims dependent thereon (2-27, 69-76 and 80-84), are not met by Maseda.

Claim 28

Reasons for which claim 28 (and claims 30-42 dependent therefrom) is/are patentable over Maseda were presented at length in Applicant's response filed May 29, 2007. These arguments were found to be persuasive.

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Claim 50

Claim 50 is directed to a device comprising: (a) an insertable body adapted for insertion into a body lumen of a patient; (b) a device lumen within said insertable body; (c) an inflatable balloon, the interior of which balloon is in fluid communication with the device lumen, and (d) one or more electrically actuated members disposed along at least a portion of the length of the device lumen. The electrically actuated members, which are adapted to transform at least a portion of the length of the device lumen between (i) a radially expanded state and (ii) a radially contracted state in which the insertable body is more readily inserted into the body lumen of the patient.

Thus claim 50 requires, inter alia, a device lumen transformable between (i) a radially expanded state and (ii) a radially contracted state, which device lumen is in fluid communication with the interior of an inflatable balloon.

Nothing resembling such a device is taught in Maseda. While Figs. 5 and 5A might arguably illustrate a device "lumen" that is transformable between (i) a radially expanded state and (ii) a radially contracted state, such a lumen is clearly not in fluid communication with the interior of the balloon due to the presence of the slits in the lumen that exist between the circumferentially spaced composite strands 500, which would render balloon inflation impossible.

For evidence of one or more electrically actuated members, which are adapted to transform at least a portion of the length of the device lumen between (i) a radially expanded state and (ii) a radially contracted state in which the insertable body is more readily inserted into the body lumen of the patient, the Examiner references col. 3, lines 2-6 ("the electroactive polymer strands may be integrated into various segments of the devices such that a section of the device expands in a manner which mimics a balloon in a balloon catheter or to expand an end of the probe to mimic an anchoring device".) However, for all described embodiments in which a lumen is arguably radially expanded in a fashion that mimics a balloon, this is accomplished by the use of multiple bendable strands which are circumferentially spaced from one another when actuated (see, e.g., Figs. 5 and 5A). Such a lumen is clearly not placed in fluid communication with the interior of the balloon, due to the presence of the spaces that exist between the circumferentially spaced composite strands 500. There is no possibility of inherency.

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For at least these reasons, it is respectfully submitted that the limitations of claim 50, and claims 51-63, 65, 66, 78 and 79 dependent thereon, are not met by Maseda.

Claims 4, 71 and 72

With respect to claim 4, Maseda does not describe a catheter wherein a deformable region is expanded in at least one radial dimension upon volumetric expansion of an active region. See also claim 71 (wherein the deformable region of claim 4 is an elongated flexible material) and claim 72 (wherein the deformable region of claim 4 is an elastic region).

Claim 5

With respect to pending claims 5 and 36, Maseda does not describe a circumferential *band* (i.e., an annulus). In Figure 3B, a *strand* 308 is wrapped in a *helical manner*. To interpret the helix formed from a strand as a "band" requires a clear distortion of the language. Thus, the limitations of claim 5 are not met by Maseda.

Claim 16

With respect to claim 16, Maseda does not describe a catheter wherein one or more active regions are disposed such that, upon expansion of the one or more active regions, at least a portion of the balloon is expanded from a first position to a second position that is radially beyond the first position.

Claim 84

Present claim 84 requires that the active region be disposed *over* an elongate body *and beneath* a balloon. Thus, claim 84 is believed to be patentable over Maseda for the same reasons as is claim 28.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 1-6, 9, 12, 13, 15, 16, 24, 25, 50, 54, 56 57, 61, 71, 72, 80 and 84 under 35 U.S.C. 102(e) over Maseda is respectfully requested.

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Rejection of claims 81-83 under 35 USC 102(e) over Couvillon US 6,679,836

Claims 81-83 have been rejected under 35 U.S.C. 102(e) as being anticipated by Couvillon. Applicant respectfully traverses this rejection and its supporting comments.

Claims 81-83 are dependent on independent claim 1 and thus contain all of the limitations of the independent claim.

Claim 1 requires that "the *medical device is expanded in at least one radial dimension* relative to said axis upon volumetric expansion of the active region." Although Couvillon disclose that the electronic polymer actuators (EAPs) themselves may expand, there is no disclosure corresponding to the emphasized limitation of a medical device that expands in at least one radial dimension relative to the axis of the elongate body upon volumetric expansion of an active region. That follows from the placement of the EAPs in the device disclosed by Couvillon, which is different from those disclosed in the present specification. It is the placement disclosed herein and recited expressly in some claims that leads to the emphasized limitation. Thus, not all of the limitations of claims 81-83 are disclosed in the reference, and there is no anticipation. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *in re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (Fed. Cir. 1978). Also see MPEP 2131.

Reconsideration and withdrawal of the rejection under 35 U.S.C. 102(e) over Couvillon is respectfully requested.

Rejection of claims 10, 11, 52, 60, 63, 73 and 74 under 35 U.S.C. 103(a)

Claims 10, 11, 52, 60, 63, 73 and 74 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda. This rejection is respectfully traversed.

As a preliminary matter, reasons for which claims 30-32 and 35 are unobvious over Maseda were presented at length in Applicant's response filed May 29, 2007. These arguments were found to be persuasive.

The fundamental defects of the Maseda reference have been discussed above. Claims 10, 11, 52, 60, 63, 73 and 74 are patentable for at least the same reasons as the independent claims from which they depend, among other reasons.

The Examiner has not presented any response to applicant's prior remarks concerning this rejection in the response to the first action on the merits.

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It bears repetition here that the Examiner has acknowledged that specific limitations have not been "directly" taught. The Examiner's reasoning that the device disclosed by the reference is *capable* of carrying out the functions recited in the present claims or *could* be modified in such a way as to result in the present claims does not provide the valid criteria for a conclusion of *prima facie* obviousness, i.e., "capable of" and "could be modified" are not the same as "obvious to." See *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (BPAI 1993).

Claim 10

The limitation of claim 10, in which the active region of claim 1 is disposed in a recess formed in the elongate body, wherein the recess is a circumferential recess, is neither taught nor suggested by the prior art.

Claims 60, 73 and 74

With regard to claims 60, 73 and 74, a disclosure of "various other configurations" does not make any specific undisclosed configuration obvious, absent some explanation based on logic and sound scientific reasoning. *Ex parte Levengood supra*. On this record there is no such explanation.

Reconsideration and withdrawal of the above rejection under 35 U.S.C. 103(a) are respectfully requested.

CONCLUSION

In light of the foregoing remarks, it is believed that all rejections of record have been obviated, and allowance of this application is respectfully requested. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

FEES

The Office is authorized to charge the two-month extension fee (\$450) and any additional fees that are due as a result of this Response, to the undersigned attorney's PTO Deposit Account #50-1047.

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Respectfully submitted,

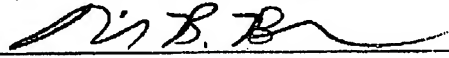


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